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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of
Jean Pierre Giraud

Serial No.: 10/683,692

Filed: October 9, 2003

For: A Lancet System Including Test Strips and Cassettes for Drawing and Sampling Bodily Material

Group Art Unit:

Examiner: Not Yet Assigned

Docket No.:
62357.012901

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-captioned application, Applicant respectfully submits the following amendment in order to more clearly define the invention as described in the "Brief Description of the Drawings" and the "Detailed Description of the Embodiments", please amend the above-identified application as follows:

* * *

CERTIFICATE OF MAIL

Date: March 19, 2004

I hereby certify that this paper, along with any document or paper referred to as being attached, is being deposited with the United States Postal Services with sufficient postage for First Class Mail under 37 CFR 1.8 in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Randi Flamenbaum
(Name of person mailing correspondence)

Randi Flamenbaum
(Signature of person mailing correspondence)

Amendment to the **"Brief Description of the Drawings"** and **"Detailed Description of the Embodiments"** are reflected below. Replacement pages are also enclosed herewith.

Brief Description of the Drawings

Page 4, after "Figure 9 is a perspective view showing yet another arrangement for linking a plurality of lancets;" please insert -- Figure 9A is a perspective view showing another arrangement for linking a plurality of lancets and test strips;--

Page 4, after "Figure 10 is a perspective view showing a cassette for storing lancets, delivering them for penetration into the person's body, and analyzing the sample taken from the person;", please add --Figure 10A is a perspective view showing another arrangement of a cassette for storing lancets and or test strips, delivering them for penetration into the person's body, and analyzing the sample taken from the person;--

Page 4 through to Page 5, after "Figure 17 is a cross sectional view of the test strip of Figure 15, taken along line B-B.", please add --Figure 18 is a perspective view showing a integrated lancet and test strip that could be used for immediate testing or transported to another location for testing.—

Detailed Description of the Embodiments

Page 7, after line 14, please add --Figure 9a shows another alternative embodiment for linking together lancets or test strips 10. They are held in sleeves formed by bonding together two layers of continuous ribbon 60. Although not shown, the continuous ribbon could have an array of holes used to drive the ribbon inside of a cassette arrangement.--

Page 8, line 12, after "lancet" please add --and or test strip--.

Page 8, after line 13, please add --In yet another embodiment, first arched shaped end 102 is provided with a membrane 122 having a slit 124 through which the head of the lancet and or test strip passes when it is activated in order to obtain a sample from a person.

In another embodiment shown in Figure 10A, the lancets are loaded into holders arranged in a continuous belt in the cassette 100. A drive gear 138 drives a rack that opens membrane 122 and contacts the lancet 10. As it moves forward a second membrane 122 is opened creating an opening 124 through which the lancet passes.

Figure 10B shows a section view of integrated lancet with several sections identified. The sensor 220 also shown in Figure 10C . Figure 10C shows an area of the lancet 10 where there is a sensor 220 created by printing or an In Mold Label process. The lancet 10 contains a spring 221 for returning the piercing element 222 to its original position. The piercing element 222 is free to move forward in the lancet, and is returned by the spring 221. In use, a pusher engages the lancet at 223 and drives it forward till it contacts the skin. The inertia of 222 continues to move it forward so that it pierces. A sample is drawn into the lancet 10 and contacts the sensor 220. Figure 10 D shows a surface for making electrical contact 224 that is created by a conductive ink that is printed or from an in mold label. The contacting surface 224 is connected to the sensor 220 by small wires or other method.—

Page 9, line 3, after “membrane” change “140” to –141--.

Page 13, after line 16, please add -- Figure 18 shows a integrated lancet and sensor that can be used to take a sample and make a measurement either immediately or transported to another location. It consists of a body 233 that hold a sensor element 232 which could be an in mold label or an assembly after molding. The sensor element 232 has an arrangement of electrodes that can be used to generate an electrical signal that can be measured. The sensor element located around the circumference of body 233. Inside the body a series of disk like elements 231 are placed with channels for transporting the blood from the center, where they are in communication with the piercing element 230 to the outer circumference, where the sensing element 232 is located. The arrangement of the disks and the relative position of the channels can control the amount of sample fluid that is collected. The piercing device in a holder 230 which could be driven by a several different mechanisms passes through the center, piercing the skin and allowing blood to form on the surface with is drawn into the channel by capillary action.--

No fee is believed to be due in connection with the filing of this paper. However, if any fee is due, the Commissioner is authorized to charge any fees, which may be required or credit any overpayment to Deposit Account No. 501561.

Respectfully submitted,

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strip as it is formed in the mold.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a lancet of the present invention;

Figure 2 is a cross sectional view of a lancet of the present invention along line A -A of Figure 1;

Figure 3 is a cross sectional view of a lancet of the present invention along line B-B of Figure 1;

Figure 4 is a schematic of a mold in which lancets of the present invention are created by an in mold labeling method;

Figure 5 is a schematic of a mold in which lancets of the present invention are created by a pad printing method;

Figure 6 is a perspective view depicting an alternative arrangement to lancets of the embodiment shown in Figure 1;

Figure 7 is a perspective view showing an arrangement for linking a plurality of lancets;

Figure 8 is a perspective view showing yet another arrangement for linking a plurality of lancets;

Figure 9 is a perspective view showing yet another arrangement for linking a plurality of lancets;

Figure 9A is a perspective view showing another arrangement for linking a plurality of lancets and test strips;

Figure 10 is a perspective view showing a cassette for storing lancets, delivering them for penetration into the person's body, and analyzing the sample taken from the person;

Figure 10A is a perspective view showing another arrangement of a cassette for storing lancets and or test strips, delivering them for penetration into the person's body, and analyzing the sample taken from the person;

Figure 11 is a cross sectional view of the cassette;

Figure 12 is a cross sectional view of the cassette drive mechanism, loaded with lancets;

Figure 13 is a perspective view showing an aspect of the cassette;

Figure 14 is a perspective view showing an aspect of the cassette;

Figure 15 is a perspective view of a test strip of the present invention;

Figure 16 is a cross sectional view of the test strip of Figure 15, taken along line A -A; and

Figure 17 is a cross sectional view of the test strip of Figure 15, taken along line B -B.

Figure 18 is a perspective view showing an integrated lancet and test strip that could be used for immediate testing or transported to another location for testing.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figure 1 shows one embodiment of a lancet 10 of the present invention. As shown, the lancet of the present invention has a body 11 and a head 12 that is provided strip as it is formed in the mold.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a lancet of the present invention;

Figure 2 is a cross sectional view of a lancet of the present invention along line A -A of Figure 1;

Figure 3 is a cross sectional view of a lancet of the present invention along line B-B of Figure 1;

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Figure 10 is a perspective view showing a cassette for storing lancets, delivering them for penetration into the person's body, and analyzing the sample taken from the person;

Figure 10A is a perspective view showing another arrangement of a cassette for storing lancets and or test strips, delivering them for penetration into the person's body, and analyzing the sample taken from the person;

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Figure 16 is a cross sectional view of the test strip of Figure 15, taken along line A -A; and

Figure 17 is a cross sectional view of the test strip of Figure 15, taken along line B -B.

Figure 18 is a perspective view showing an integrated lancet and test strip that could be used for immediate testing or transported to another location for testing.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figure 1 shows one embodiment of a lancet 10 of the present invention. As shown, the lancet of the present invention has a body 11 and a head 12 that is provided

7. Load the lancets in a cassette or other distribution device; and
8. Close the cassette.

Figures 7, 8, and 9, depict another embodiment showing a manner of unitizing a number of lancets in order to retain, package and load them into a dispensing device. In Figures 7 and 8, the lancets are mounted to a continuous ribbon or sheet 60. The film is advanced in the injection-molding machine, and the lancets are molded directly on the film. The lancets are attached so that at least the heads 12 extend over the ribbon. In the embodiment of Figure 8, the lancets are arranged on both sides of the ribbon, which is cut in the middle, to provide two sheets of lancets. In a further embodiment, a conductive material can be printed on the ribbon in a separate operation, or pad printed onto it in the mold. The ribbon, with the conductive material, can be used to test the conductive performance of the disposable units, providing an on-line quality testing system during manufacturing. Figure 9 shows an alternative embodiment for unitizing lancets, in which collapsible accordion-like appendages 58 link individual lancets. In this case, the lancets are pad printed. Figure 9A shows another alternative embodiment for linking together lancets or test strips 10. They are held in sleeves formed by bonding together two layers of continuous ribbon 60. Although not shown, the continuous ribbon could have an array of holes used to drive the ribbon inside of a cassette arrangement.

In one embodiment, 50 to 100 lancets are linked together as described herein. In yet another embodiment, an identifying tag, such as a bar code, is applied to each individual lancet, and/or ribbon. The code can be used to identify product lot number, and in the case where sample analysis occurs at a location different from where the sample is taken (such as a diagnostic laboratory), it can be used to supply information about who drew the sample, when it was drawn, and from whom the sample was drawn, to name three possible pieces of information. Also, where the sample is to be sent off to an offsite lab, the area where the chemical reagent is positioned may incorporate preservatives (i.e., EDTA, Heparin, etc) to insure the sample remains viable.

The Cassette

In a further embodiment, a cassette holds multiple lancets, typically 50 and 100 units. One embodiment of the cassette 100 is shown in Figure 10. The cassette 100 is provided with first and second arched shaped ends 102, 104, and sidewalls 106, 108, and arcuate top surface 110, each of which are joined to the ends 102, 104. It should be understood that other shapes can be adapted for the cassette.

The cassette has an opening 112 positioned on the arcuate top surface 110. Here, the opening 112 is shown as having straight sides and rounded edges, though other

7. Load the lancets in a cassette or other distribution device; and
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In one embodiment, 50 to 100 lancets are linked together as described herein. In yet another embodiment, an identifying tag, such as a bar code, is applied to each individual lancet, and/or ribbon. The code can be used to identify product lot number, and in the case where sample analysis occurs at a location different from where the sample is taken (such as a diagnostic laboratory), it can be used to supply information about who drew the sample, when it was drawn, and from whom the sample was drawn, to name three possible pieces of information. Also, where the sample is to be sent off to an offsite lab, the area where the chemical reagent is positioned may incorporate preservatives (i.e., EDTA, Heparin, etc) to insure the sample remains viable.

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The cassette has an opening 112 positioned on the arcuate top surface 110. Here, the opening 112 is shown as having straight sides and rounded edges, though other shapes are possible. In one specific embodiment, the edges of the opening are lined with an elastomeric material 114, which extends into the interior of the cassette. In another example, on the interior of the cassette, in the area of the arcuate top surface 110, a window 116 is mounted to the twin axis 118. The window is rotatable between an open position and a closed position by a rack and pinion arrangement. The window closes when the cassette nears its final position in the diagnostic kit, which is provided with a rack which engages axis 118 for opening the window 116 through the membrane 120 provided on second arched shaped end 104.

In yet another embodiment, first arched shaped end 102 is provided with a membrane 122 having a slit 124 through which the head of the lancet and or test strip passes when it is activated in order to obtain a sample from a person.

In another embodiment shown in Figure 10A, the lancets are loaded into holders arranged in a continuous belt in the cassette 100. A drive gear 138 drives a rack that opens membrane 122 and contacts the lancet 10. As it moves forward a second membrane 122 is opened creating an opening 124 through which the lancet passes.

Figure 10B shows a section view of integrated lancet with several sections identified. The sensor 220 also shown in Figure 10C. Figure 10C shows an area of the lancet 10 where there is a sensor 220 created by printing or an In Mold Label process. The lancet 10 contains a spring 221 for returning the piercing element 222 to its original position. The piercing element 222 is free to move forward in the lancet, and is returned by the spring 221. In use, a pusher engages the lancet at 223 and drives it forward till it contacts the skin. The inertia of 222 continues to move it forward so that it pierces. A sample is drawn into the lancet 10 and contacts the sensor 220. Figure 10 D shows a surface for making electrical contact 224 that is created by a conductive ink that is printed or from an in mold label. The contacting surface 224 is connected to the sensor 220 by small wires or other method.

The cassette is provided with an interior housing 130 into which the lancets are loaded. As shown in an embodiment of Figure 12, the lancets 10 are attached to the ribbon 60, and the ribbon and lancets are loaded into the interior housing in a serpentine arrangement. The lancets and ribbon fill the interior housing and are loaded into the distribution wheel 132, which indexes the lancets in preparation for their activation, and drawing of a sample. As shown, the distribution wheel 132 has four slots 134, though additional slots may be provided. The axis 136 of the distribution wheel is mounted to the twin axis 117 provided on the cassette 100. The activation position is the uppermost slot 134' and the lancet in this slot engages with a driver, such as gear wheel 138, which moves the lancet out of the cassette and diagnostic kit, in order to take a sample. The distribution wheel 134 is provided with a series of indents 135, which receive a cutting blade 137 which cuts the ribbon of the lancet that is positioned in the activation slot 134'.

To draw a sample, shown in one embodiment as illustrated in Figure 12, the user activates the device by issuing the appropriate command on the diagnostic kit, such as by pressing a button. In another embodiment, the membrane 124 is pressure sensitive and acts as switch, so that when the pusher mechanism is pressed against the user's skin, at the location where a sample is to be drawn, the stepper motor (or other suitable device) is activated, driving the lancet out of the cassette. In any event, when the stepping motor is activated, it drives a device such as the gear wheel 138 shown in Figures 12 and 13, which is engaged with the rack and pinion arrangement 24' of Figure 6. The stepping shapes are possible. In one specific embodiment, the edges of the opening are lined with an elastomeric material 114, which extends into the interior of the cassette. In another example, on the interior of the cassette, in the area of the arcuate top surface 110, a window 116 is mounted to the twin axis 118. The window is rotatable between an open position and a closed position by a rack and pinion arrangement. The window closes when the cassette nears its final position in the diagnostic kit, which is provided with a rack which engages axis 118 for opening the window 116 through the membrane 120 provided on second arched shaped end 104.

In yet another embodiment, first arched shaped end 102 is provided with a membrane 122 having a slit 124 through which the head of the lancet and or test strip passes when it is activated in order to obtain a sample from a person.

In another embodiment shown in Figure 10A, the lancets are loaded into holders arranged in a continuous belt in the cassette 100. A drive gear 138 drives a rack that opens membrane 122 and contacts the lancet 10. As it moves forward a second membrane 122 is opened creating an opening 124 through which the lancet passes.

Figure 10B shows a section view of integrated lancet with several sections identified. The sensor 220 also shown in Figure 10C. Figure 10C shows an area of the lancet 10 where there is a sensor 220 created by printing or an In Mold Label process. The lancet 10 contains a spring 221 for returning the piercing element 222 to its original position. The piercing element 222 is free to move forward in the lancet, and is returned by the spring 221. In use, a pusher engages the lancet at 223 and drives it forward till it contacts the skin. The inertia of 222 continues to move it forward so that it pierces. A sample is drawn into the lancet 10 and contacts the sensor 220. Figure 10 D shows a surface for making electrical contact 224 that is created by a conductive ink that is printed or from an in mold label. The contacting surface 224 is connected to the sensor 220 by small wires or other method.

The cassette is provided with an interior housing 130 into which the lancets are loaded. As shown in an embodiment of Figure 12, the lancets 10 are attached to the ribbon 60, and the ribbon and lancets are loaded into the interior housing in a serpentine arrangement. The lancets and ribbon fill the interior housing and are loaded into the distribution wheel 132, which indexes the lancets in preparation for their activation, and drawing of a sample. As shown, the distribution wheel 132 has four slots 134, though additional slots may be provided. The axis 136 of the distribution wheel is mounted to the twin axis 117 provided on the cassette 100. The activation position is the uppermost slot 134' and the lancet in this slot engages with a driver, such as gear wheel 138, which moves the lancet out of the cassette and diagnostic kit, in order to take a sample. The distribution wheel 134 is provided with a series of indents 135, which receive a cutting blade 137 which cuts the ribbon of the lancet that is positioned in the activation slot 134'.

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In another embodiment, a protective film covers the surface of the skin pusher to prevent carryover of sample from test to test or collection to collection. The tip penetrates the protective film during a sampling cycle. The protective film is indexed to a new position for the next sampling cycle.

In the embodiment relating to a chemical assay, when the sample enters the area where the chemical reagent is positioned, a chemical reaction between the two takes place. The reaction may yield qualitative information, such as a color change, which the user analyzes by visual observation, or which is analyzed by the device. Alternatively, where the lancets are provided with the previously described electrical contacts, the chemical reaction may create an electrical potential between the proximal laterally extending portions 19a and 20a of contacts and the distal laterally extending portions 19c and 20c of contacts. The lancet is placed in electrical contact with electronics of the diagnostic kit. The potential is measured by the diagnostic device, and converted to useful information. For example, where the sample is blood, the potential can yield information on the user's blood sugar. This information is displayed on a window on the device.

In one embodiment, when the user takes the next test, a motor rotates the distribution wheel 132. For example, as shown in Figure 12, the wheel is rotated in a motor turns the gear wheel in a direction that drives the lancet towards the membrane 122, and the slit 124. The skin pusher 140 is moved back into the cassette, and contacts a membrane that is provided with an opening 142. The pusher opens the membrane [140] 141, and the head of the lancet passes through the opening. The lancet penetrates the skin of the user, drawing a sample of fluid, such as blood. The blood enters the grooves on the lancet through the collecting zone, and is transferred by capillary action to the area where the chemical reagent is located. After a short period, the sample is collected. This process may take about a fraction of a second, which may be about 0.1 second. The lancet is retracted, by reversing the direction of the stepping motor. Optionally, the device emits an audible sound that notifies the user that the sampling process is completed. Once sample is collected, and the lancet retracted, the skin pusher returns to its original position. The membrane closes and re-establishes a moisture-tight seal in the meter.

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In one embodiment, when the user takes the next test, a motor rotates the distribution wheel 132. For example, as shown in Figure 12, the wheel is rotated in a with a window or windows through which a sample can be deposited on the strip, and through which the strip may be analyzed. When all of the strips are used, the lancet is discarded and a replaced with a new lancet with the appropriate units (e.g. 50). A desiccant plastic can be used to line at least a portion inside of the lancet drum. For example, a desiccant plastic disclosed in U.S. Patent No. 6,174,852 may be employed here.

Figure 18 shows an integrated lancet and sensor that can be used to take a sample and make a measurement either immediately or transported to another location. It consists of a body 233 that hold a sensor element 232 which could be an in mold label or an assembly after moldering. The sensor element 232 has an arrangement of electrodes that can be used to generate an electrical signal that can be measured. The sensor element located around the circumference of body 233. Inside the body a series of disk like elements 231 are placed with channels for transporting the blood from the center, where they are in communication with the piercing element 230 to the outer circumference, where the sensing element 232 is located. The arrangement of the disks and the relative position of the channels can control the amount of sample fluid that is collected. The piercing device in a holder 230 which could be driven by a several different mechanisms passes through the center, piercing the skin and allowing blood to form on the surface with is drawn into the channel by capillary action.

What follows is a listing of tests and test systems listed in part 862 of Title 21 of the Code of Federal Regulations. The embodiments disclosed herein can be employed in conducting at least some of the tests enumerated below:

Part 862 - Clinical chemistry and clinical toxicology devices

Subpart A--General Provisions

§862.1 - Scope.
§862.2 - Regulation of calibrators.
§862.3 - Effective dates of requirement for premarket approval.
§862.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B--Clinical Chemistry Test Systems

§862.1020 - Acid phosphatase (total or prostatic) test system.
§862.1025 - Adrenocorticotropic hormone (ACTH) test system.
§862.1030 - Alanine amino transferase (ALT/SGPT) test system.
§862.1035 - Albumin test system.
§862.1040 - Aldolase test system.
§862.1045 - Aldosterone test system.
§862.1050 - Alkaline phosphatase or isoenzymes test system.
§862.1060 - Delta-aminolevulinic acid test system.
§862.1065 - Ammonia test system.
§862.1070 - Amylase test system.

§862.1075 - Androstenedione test system.
§862.1080 - Androsterone test system.
§862.1085 - Angiotensin I and renin test system.
§862.1090 - Angiotensin converting enzyme (A.C.E.) test system.
§862.1095 - Ascorbic acid test system.
§862.1100 - Aspartate amino transferase (AST/SGOT) test system.
§862.1110 - Bilirubin (total or direct) test system.
§862.1113 - Bilirubin (total and unbound) in the neonate test system.
§862.1115 - Urinary bilirubin and its conjugates (nonquantitative) test system.
§862.1117 - B-type natriuretic peptide test system.
§862.1118 - Biotinidase test system.
§862.1120 - Blood gases (PCO2, PO2) and blood pH test system.
§862.1130 - Blood volume test system.

with a window or windows through which a sample can be deposited on the strip, and through which the strip may be analyzed. When all of the strips are used, the lancet is discarded and a replaced with a new lancet with the appropriate units (e.g. 50). A desiccant plastic can be used to line at least a portion inside of the lancet drum. For example, a desiccant plastic disclosed in U.S. Patent No. 6,174,852 may be employed here.

Figure 18 shows an integrated lancet and sensor that can be used to take a sample and make a measurement either immediately or transported to another location. It consists of a body 233 that hold a sensor element 232 which could be an in mold label or an assembly after moldering. The sensor element 232 has an arrangement of electrodes that can be used to generate an electrical signal that can be measured. The sensor element located around the circumference of body 233. Inside the body a series of disk like elements 231 are placed with channels for transporting the blood from the center, where they are in communication with the piercing element 230 to the outer circumference, where the sensing element 232 is located. The arrangement of the disks and the relative position of the channels can control the amount of sample fluid that is collected. The piercing device in a holder 230 which could be driven by a several different mechanisms passes through the center, piercing the skin and allowing blood to form on the surface with is drawn into the channel by capillary action.

What follows is a listing of tests and test systems listed in part 862 of Title 21 of the Code of Federal Regulations. The embodiments disclosed herein can be employed in conducting at least some of the tests enumerated below:

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§862.1030 - Alanine amino transferase (ALT/SGPT) test system.
§862.1035 - Albumin test system.
§862.1040 - Aldolase test system.
§862.1045 - Aldosterone test system.
§862.1050 - Alkaline phosphatase or isoenzymes test system.
§862.1060 - Delta-aminolevulinic acid test system.
§862.1065 - Ammonia test system.
§862.1070 - Amylase test system.

§862.1075 - Androstenedione test system.
§862.1080 - Androsterone test system.
§862.1085 - Angiotensin I and renin test system.
§862.1090 - Angiotensin converting enzyme (A.C.E.) test system.
§862.1095 - Ascorbic acid test system.
§862.1100 - Aspartate amino transferase (AST/SGOT) test system.
§862.1110 - Bilirubin (total or direct) test system.
§862.1113 - Bilirubin (total and unbound) in the neonate test system.
§862.1115 - Urinary bilirubin and its conjugates (nonquantitative) test system.
§862.1117 - B-type natriuretic peptide test system.
§862.1118 - Biotinidase test system.
§862.1120 - Blood gases (PCO2, PO2) and blood pH test system.
§862.1130 - Blood volume test system.